7 510(k) SUMMARY

7.1 Company and Product Information

SEP 20 2006

Company	Life Recovery Systems HD, LLC The Sid Wolvek Research Center 170 Kinnelon Road, Suite 9 Kinnelon, NJ 07405 Phone 973.283.2800 Fax 973.283.2910 Email research@life-recovery.com
Contact Person	Robert B. Schock, Ph.D. Vice President, Research and Development
Date of 510(k) Summary	September 19, 2006
Trade Name	ThermoSuit System™
Classification Name	Thermal Regulating System
Regulation	21 CFR 870.5900
Class	II
Product Code	NZE
Predicate Device	MTA 6900 Medi-Therm III Hyper/Hypothermia System with HP7010 Hyper/Hypothermia Blanket. The predicate device is a modification of a previous version, MTA5900 Medi-Therm II Hyper/Hypothermia System, K912051.

7.2 Device Description

The ThermoSuit System (TSS) is a device that allows rapid patient cooling by the circulation of cold water in direct contact with the skin of the patient. Patient temperature measurements control the extent and duration of cooling, by controlling pump output and drainage of cooling fluid. Temperature measurements and associated alarm signals are designed to prevent overcooling.

The ThermoSuit System™ consists of the following main components:

- ThermoSuit Body Enclosure

  An inflatable mattress lies beneath the patient, and a top sheet covers most of the patient (excluding the face). Both the mattress and the top sheet have integral fluid channels that bring circulating water in direct contact with the skin. An integral Level Control Assembly maintains the fluid height in the suit.

- Multi-lumen Umbilicus Hose

  A Multi-lumen Umbilicus Hose connects the ThermoSuit Body Enclosure to the pump assembly via single twist on connector housings.

- Reservoir/Pump Assembly

  The Reservoir/Pump Assembly consists of the pump drive units and reservoir bag integrated into a single assembly for quick drop-in installation.

- Pump Controller Console

  The Pump Controller Console contains all the electronics, pneumatics and motor drives for the system. User controls are operated from a touchscreen display that is swivel mounted to adjust to user preference. A reusable temperature probe cable is included with the unit.

- Other Components

  Disposables kit also contains: Operator's Manual (PN 53001), a T-Type esophageal thermocouple probe and a ThermoSuit Patch Kit (PN 73006).

7.3 Device Functions

A patient who requires cooling is placed into the mattress of the ThermoSuit Body Enclosure. In use, the mattress is inflated with air and conforms to the shape and size of the patient. A polyurethane top sheet is attached to the rim of the inflated ThermoSuit with Velcro strips and covers the patient up to the level of the neck. Both the mattress and the top sheet have built-in flow channels that allow water to be pumped against the patient's skin for heat exchange. The mattress has a porous lining (polyester batting) that aids fluid circulation, and a drain channel system that returns water to the Level Control Assembly.

Patient temperature is monitored by means of an esophageal temperature probe. Alternatively, patient temperature may be measured with a nasopharyngeal temperature probe.

The target temperature for the treatment is entered on the touch screen, and cooling therapy is initiated. Cold water is circulated through the top and the bottom of the ThermoSuit Body Enclosure, drips on the patient, and is returned to the polyurethane reservoir in the Reservoir/Pump Assembly.

When the patient temperature approaches the target temperature, the Pump Controller Console alerts the user and purges the water from the ThermoSuit Body Enclosure. Water may also be purged by manual control.

7.4 Standards Met by New Device

ISO 10993: - Biocompatibility for short-term skin contact

UL 60601-1 – UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety First Edition
CSA C22.2 NO 601.1-M90 – Issue 1990/01/11 (R2001) Medical Electrical Equipment – Part 1: General Requirements for Safety General Instruction No 1; Supplement 1; 1994; Amendment 2 - February 1998 (R1997)

CENELEC EN 60601-1 – Medical Electrical Equipment Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amendments A1: 1993, A11: 1993, A12: 1993, A2: 1995 and A13: 1996; IEC 601-1: 1988 + A1: 1991 + A2: 1995 + Corrigendum 1995, Modified

CENELEC EN 60601-1-2 – 2001 - Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-1-2: 2001

IEC 60601-1-2 (1993-04) – Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility – Requirements and Tests First Edition; (CENELEC EN 60601-1-2: 1993)

JIS T0601-1 – Medical Electrical Equipment – Part 1: General Requirements for Safety

7.5 Intended Use

The ThermoSuit System is intended for

a. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients;
b. Monitoring of patient temperature

The intended use for the ThermoSuit System is narrower than that for the predicate device which has both cooling and warming functions.

7.6 Substantial Equivalence Determination

The ThermoSuit System™ is substantially equivalent to the predicate device in its cooling function; unlike the predicate device, it has no warming function.

The ThermoSuit System™ is substantially equivalent to the predicate device with regard to:

- removal of thermal energy from the patient
- use of a pump-driven circulation system for the cooling fluid
- use of chilled water as cooling fluid
- utilization of a large part of the patient's surface for cooling
- components:
  - a flexible polymer component filled with cooling fluid
  - a flexible piping system
  - a software-controlled pump
- utilization of the device in the hospital
- human factors:
  - operators must place the patient on the heat-exchange device
- safety systems:
  - a temperature probe in the patient controls the pumping system
  - software in the pumping system alerts the user to potential excess cooling

7.7 Performance Testing

The ThermoSuit Body Enclosure was tested with human volunteers; the results were used to optimize suit dimensions and operating parameters.

Performance testing of the ThermoSuit Body Enclosure included a 50% excess pressure of the air compartments and fluid channels; all suits passed testing.

The ThermoSuit System was functionally tested with new and aged ThermoSuit Body Enclosures by measuring the relevant design parameters; the product met all performance specifications.

Performance testing of the ThermoSuit System included a full evaluation of the Pump/Controller functions and software validation; the results conformed to the device specifications.

Cooling studies comparing the ThermoSuit System and the predicate device were run in two models:

(1) Heated mannequin comparative cooling bench study
(2) Animal study (large pigs) with ThermoSuit's adapted to the animal's shape.

The results were comparable insofar as the new device and the predicate device both cooled the test systems, but cooling occurred at a higher rate in the new device.

7.8 Design Validation

The design was validated during functional testing by four (4) Users; completing a total of nine (9) test runs. Monitoring of water volumes in the ThermoSuit Body Enclosure and reservoir were made during system operation and showed that the system worked in the hands of users. The users' responses to a detailed questionnaire established that they understood the Operator's Manual, the device and its' operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2006

Life Recovery Systems HD, LLC
c/o Robert B. Schock, Ph.D.
Vice President, Research and Development
The Sid Wolvek Research Center
170 Kennelon Road, Suite 9
Kennelon, NJ 07405

Re: K061023
ThermoSuit Systems™
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NZE
Dated: August 10, 2006
Received: August 11, 2006

Dear Dr. Schock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean

that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8 Indications for Use

510(k) Number K061023

Device Name: ThermoSuit System™

Indications for Use

The ThermoSuit System™ is a thermal regulating system.

Indications for Use are

a. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients;
b. Monitoring of patient temperature.

Patient Population

The ThermoSuit System™ (Size M) is indicated for patients

- greater than 58" (147 cm) and less than 75" (190 cm) in height
- and less than 26" (66 cm) in width.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061023